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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,789	04/15/2004	Douglas A. Hettrick	P-10880.00	6661

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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	**PAPER NUMBER**
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,789	HETTRICK ET AL.	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/02/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 2 October 2006 was filed after the mailing date of the Office Action on 31 July 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 12, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. The limitation of a "sudden increase" in the frequency of first events has not be sufficiently defined in the original Specification to determine that which would and would not qualify as "sudden." For instance, two successive beats are sufficient to determine an increase in event frequency, and would be considered sudden in that they take only a few seconds or less to occur. Likewise, monitoring a trend increase over several

hours could be considered a sudden increase in the case where trends are usually expected to take days or weeks to develop.

5. The limitation that "the increase of the first events be detected over a period of time of approximately one minute" is not supported in the Specification. While paragraph [45] does mention various time periods that can be observed, it is noted that these time periods are in reference to the changes in overdrive pacing rate (i.e. the resultant therapy of the monitored signals) and not the monitored first events themselves (i.e. PACs, the variables monitored to determine the resultant therapy). For this reason, it is considered that a specific time period or acceptable range of time periods for the monitored first events has not been properly set forth in the disclosure.

6. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7, 12-18, 23 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by Mehra et al (U.S. 6185459, hereinafter Mehra'459) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mehra'459.

Referring to claims 1-2, 12-13, 23 and 24, Mehra'459 teach a pacemaker that delivers tachyarrhythmia prevention therapy for an extended period of time (see

Abstract). The pacemaker can employ a metric to determine if therapy is successful. The metric measured can be the frequency of occurrence of PACs, and further may be a defined range of PACs per hour, determined by the physician to represent an acceptable range of occurrences of PACs. The aggressiveness of the atrial arrhythmia prevention pacing modality employed may be increased in response to the number of occurrences of PACs being in excess of the defined endpoint range (see column 4, lines 5-12 and lines 30-38).

Further regarding claims 1, 12, 23 and 24, Mehra'459 is considered to disclose a means for detecting a sudden increase in the frequency of PACs insomuch as a change over a two-day period can be considered "sudden" in comparison to trends measured over weeks or months. Alternatively, even though the device of Mehra'459 is disclosed to monitor trends over certain periods of time with the examples of days, weeks or months, this does not preclude monitoring over shorter periods, also able to be considered of a sudden nature. Further, the Mehra'459 inherently must measure each heartbeat or PAC in order to trend such a statistic over a longer period of time, and therefore inherently detects changes on a beat-to-beat basis, which qualifies as a sudden increase.

Still further regarding claims 1, 12, 23 and 24, Mehra'459 inherently detects increases over a period of up to approximately one minute, since the Mehra'459 device can detect increases of periods longer than that, e.g. up to a period of days, weeks or months. Detecting increase over a two-day period inherently includes detecting increases over a time period of approximately one minute. Alternatively, it would have

been obvious to one having ordinary skill in the art at the time of the invention to detect increases in first event frequency over a time period of one minute, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art. In this case, it would be obvious to measure increase over time periods of one minute when the intention is to update the delivered therapy on a more frequent basis.

Regarding claims 3 and 14, Mehra'459 teach that in response to an increase in PACs/day, the rate of the therapy may be increased (see column 21, lines 65-67 and column 22, lines 1-10). With reference to claims 4-5 and 15-16, Mehra'459 teach the device described above and further disclose that certain endpoints such as PACs/day and AF/day may be defined for a 24-hour period. Due to one or both of the PAC/day and AF/day values exceeding the defined acceptable ranges, the pacing parameters are adjusted to be more aggressive by either increasing or decreasing the rate. During a new 24-hour period, data is collected with the newly adjusted endpoints (see column 21, lines 57-67 and column 22, lines 1-15). With regards to claims 6-7 and 17-18, Mehra'459 disclose that the metric used to optimize the parameters of the arrhythmia prevention pacing modality may also be employed to disable the arrhythmia prevention pacing modality or to trigger the switch to an alternative pacing prevention modality (see column 4, lines 45-51). While not stated explicitly, it is inherent that arrhythmia

detection subsequent to therapy is employed since the therapy is arrhythmia prevention pacing modality, and detecting an arrhythmia would prove the pacing to be ineffective.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 8-11 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra'459.

Mehra'459 disclose the claimed invention except for determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold. It would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method for controlling therapy in an implantable medical device as taught by Mehra et al, with determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold since it was known in the art that determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold is used to provide accurate and effective therapy and to prevent further damage to the patient.

Additionally, Mehra'459 disclose the claimed invention but do not disclose expressly the determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system and method for controlling therapy in an implantable medical device as taught by Mehra'459 with the determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold, because Applicant has not disclosed that determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a

predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with determining whether the second event is detected subsequent to delivery of therapy and determining whether therapy has been delivered for a predetermined time threshold (see figure 11), because it is used to provide accurate and effective therapy and to prevent further damage to the patient and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Mehra'459 Therefore, it would have been an obvious matter of design choice to modify Mehra'459 to obtain the invention as specified in the claims.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

22 March 2007

George Manuel
Primary Examiner